



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/380,200	01/30/1995	MAX L. BIRNSTIEL	0652.1080001	5449

7590 11/03/2003

STERNE KESSLER GOLDSTEIN & FOX
SUITE 600
1100 NEW YORK AVENUE NW
WASHINGTON, DC 200053934

EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/380,200	BIRNSTIEL ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) 3-7, 11, 12, 15, 16, 21-27, 30-33, 35, 37 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8, 13, 14, 17-20, 28, 36, 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

1. This application is a continuation of 07/946,498.
2. Claims 1-33 and 35-42 are pending.
3. Claims 3-7, 11-12, 15-16, 21-27, 30-33, 35, 37 and 42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 8, 13, 14, 17-20, 28, 36, 38-41 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,144,019, of record, in view of U.S. Patent 5,166,320 and U.S. Patent 5,428,132, all of record for reasons set forth in the Office Action mailed 1-23-03.

Applicant's arguments have been fully considered but are not found persuasive.

Applicant argues that the since the '320 patent has an earlier filing date than '019 patent and since the '019 patent does not teach or suggest that its method has problems, and that the '320 patent provides no comparative data which demonstrates that their claimed methods are superior to their gene delivery methods there would be no motivation to arrive at Applicant's claimed invention.

However, the burden on the Examiner is to determine what one of ordinary skill in the art at the time the application was filed would have determined to be obvious in view of what was known to those of skill in the art at that time, not when each teaching was taught but what was collectively known by those of skill in the art at the time the invention was made. In regards to

Art Unit: 1644

Applicant assertion that the '320 patent provides no comparative data demonstrating superiority of their claimed gene delivery methods, motivation does require actual demonstration of superior results, only a reason why one would be motivated to arrive at Applicant's claimed invention with a reasonable expectation of success in creating Applicant's invention.

Applicant argues that Verma et al., exhibit A characterizes the state of the art to be that virtually all gene delivery methods had some problems, so that to indicate there are general disadvantages associated with use of one type of gene deliver method does not provide suggestion to utilize another. In addition Applicant argues there is no specific incentive to use the antibody-polycation-polynucleotide delivery system to target T cells.

However, the problem of delivering polynucleotides using liposomes is overcome by using the claimed antibody polycation delivery system, as taught by the '320 patent. This is a specific problem which the prior art specifically teaches how it can be overcome by the prior art. In addition, targeting T cells with genes was already known, as is taught by the '019 patent, what is obvious is to target T cells using the gene delivery method taught by the '320 patent for reasons discussed in the original rejection. There is a specific teaching to modify the gene delivery system of the '019 patent with that of the '320 patent.

Applicant argues that Hirsch et al., teaches away from the claimed invention. Applicant argues that the '132 patent teaches less components to successfully target DNA to T cells

The '132 patent is relied upon for teaching how one of skill in the art would target T cells with antibodies. Nowhere does the '132 patent teach that the gene delivery system taught by the '320 patent should not be used.

Applicant argues that there is no reasonable expectation of success to arrive at Applicant's claimed invention. They provide art references to demonstrate that HIV infection of T cells leads to a loss of CD4 from cell surfaces.

However, the claims are being construed as they read upon using CD3 as a target for the gene delivery construct, not CD4. In addition it is noted that all the claims require is that the complex is taken up by the cells, the '132 patent teaches their anti-CD3 polynucleotide complex when bound by CD3 on T cells is taken up by the cells. As for the rest of Applicant assertions on expectation of success, Applicant is guided to MPEP 2145, which states that Applicant arguments do not replace evidence where evidence is required.

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1644

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 8:30 to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973.

A handwritten signature in cursive script, appearing to read "Patrick J. Nolan".

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

10/31/03